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510 (k) Summary

In accordance with section 513(I) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

Tyco Healthcare/Kendall
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: March 29, 2004

1. Contact Person

Wei Zhao
Senior Specialist, Regulatory Affairs
Tyco Healthcare/Kendall
Telephone: (508) 261-8404
Fax: (508)261-8461

2. Name of Medical Device

Classification Name:	Urological catheter and accessories
Common or Usual Name:	Urinary Drainage Catheter

3. Identification of Legally Marketed Device

The proposed Tyco Healthcare/Kendall ***DOVER® ROB-NEL* Catheter** is substantially equivalent in intended use, function and mode of operation to the Tyco Healthcare/Kendall **DOVER® *ROB-NEL* Catheter**, which is currently marketed under 510(k) number K810216.

4. Device Description

The Tyco Healthcare/Kendall ***DOVER® ROB-NEL* Catheter** is a sterile, single use, Intermittent urinary drainage catheter extruded from thermo-sensitive Polyvinyl chloride (PVC) material.

5. Device Intended Use

The product is intended for intermittent catheterization to drain urine from the urinary bladder. The product is intended for use on patients who are not capable of voluntary urination.

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6. Product Comparison

The proposed ***DOVER® ROB-NEL* Catheter** is substantially equivalent to the predicate device in that each product has the same intended use and same physical, functional and performance characteristics. The proposed and predicate devices are made from the same materials and have the same design.

7. Nonclinical Testing

Biocompatibility testing has demonstrated that it meets the requirements of guidelines presented in the 10993 ISO Standard, Part 1, with the FDA modified matrix presented in memorandum G95-1.

End of Document

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2004

Ms. Wei Zhao
Senior Regulatory Specialist
Tyco Healthcare
The Kendall Company
15 Hampshire Street
MANSFIELD MA 02048

Re: K040897
Trade/Device Name: Tyco Healthcare/Kendall ***DOVER® ROB-NEL*** Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 KOD
Dated: June 22, 2004
Received: June 23, 2004

Dear Ms. Zhao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use Statement

510 (k) Number (if known): K040897

Device Name:

Tyco Healthcare/Kendall ***DOVER® ROB-NEL*** **Catheter**

Indications for Use:

The proposed device is intended for use in the drainage of urine from the urinary bladder. The product is intended for intermittent catheterization on patients who are not capable of voluntary urination. This product is not designed for use as an indwelling catheter.

Please DO NOT Write Below This Line – Continue On Another Page if Needed

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _X___ OR OVER-The –Counter Use _____ (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040897